



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public symposium.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm From Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied.

DATES: The public symposium will be held on June 15, 2017, from 8 a.m. to 4 p.m.

ADDRESSES: The public symposium will be held at FDA's White Oak campus, 10903 New Hampshire Ave, Bldg. 31 (The Great Room C), Silver Spring, MD 20903. Entrance for the public symposium participants (non-FDA employees) is through Bldg. 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Christine Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-4228, email: CDERSafeUseInitiative@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, Professional Affairs and Stakeholder Engagement Staff (PASES), is hosting a 1-day public symposium entitled "Safe Use Symposium: A Focus on Reducing Preventable Harm from Drugs in the Outpatient Setting." The purpose of this symposium is to discuss sources of preventable harm from drugs in the outpatient setting, such as the use of inappropriate medications in particular age groups, drug-drug interactions, unintended exposures, and misuse; and to stimulate the exchange of ideas among thought leaders on interventions to reduce preventable harms and how these interventions can be studied. This information may assist FDA in identifying significant and unexplored areas of preventable harm from drugs for the purpose of funding future research through the Safe Use Initiative. The symposium will feature presentations on sources of outpatient preventable harms, possible interventions, and future research topics. Areas to be discussed include identifying drugs and populations associated with a higher risk of preventable harm, as well as events which may be amenable to interventions. Methods to measure the effect of interventions and how to apply these to the outpatient setting will also be an important focus of discussion.

Presenters will represent multidisciplinary backgrounds from government, academia, patient safety groups, health care industry, and clinicians. There will be opportunities for interaction between speakers and attendees as well as question and answer sessions.

Registration: There is no registration fee to attend the public symposium. Early registration is recommended because seating is limited, and registration will be on a first-come,

first-served basis. There will be no onsite registration. Persons interested in attending this symposium must register online at

<http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm538670.htm?SSContributor=true>. For those without Internet access, please contact Christine Lee (see FOR FURTHER INFORMATION CONTACT) to register. If you need special accommodations due to a disability, please contact Christine Lee at least 7 days in advance.

Transcripts: A transcript of the symposium will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at <https://www.regulations.gov> approximately 30 days after the symposium. Transcripts will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <https://www.fda.gov>.

Dated: April 17, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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